Scientific opinion on an application for renewal of authorisation for continued marketing of maize 59122 and derived food and feed submitted under articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences LLC

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EFSA Panel on Genetically Modified Organisms (GMO),
Hanspeter Naegeli, Andrew Nicholas Birch, Josep Casacuberta, Adinda De Schrijver, Mikołaj Antoni Gralak, Philippe Guerche, Huw Jones, Barbara Manachini, Antoine Messéan, Elsa Ebbesen Nielsen, Fabien Nogué, Christophe Robaglia, Nils Rostoks, Jeremy Sweet, Christoph Tebbe, Francesco Visioli, Jean-Michel Wal, Fernando Álvarez, Michele Ardizzone and Kostas Paraskevopoulos

Abstract

Following the submission of application EFSA-GMO-RX-003 under Regulation (EC) No 1829/2003 from Pioneer Overseas Corporation and Dow AgroSciences LLC, the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific risk assessment on the data submitted in the context of the renewal of authorisation application of the insect-resistant genetically modified maize 59122. The data received in the context of this renewal application contained post-market environmental monitoring reports, a systematic search and evaluation of literature, updated bioinformatics analyses, and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application. Under the assumption that the DNA sequence of the event in maize 59122 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that no new hazards or modified exposure and no new scientific uncertainties were identified that would change the conclusions of the original risk assessment on maize 59122.

Keywords: maize, 59122, renewal, articles 11 and 23, Regulation (EC) No 1829/2003

Requestor: European Commission (DG SANTE)

Question number: EFSA-Q-2016-00526

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Summary

Following the submission of application EFSA-GMO-RX-003 under Regulation (EC) No 1829/2003[1] from Pioneer Overseas Corporation and Dow AgroSciences LLC, the Panel on Genetically Modified Organisms of the European Food Safety Authority (GMO Panel) was asked to deliver a scientific opinion on the data submitted in the context of the renewal of authorisation application of the insect resistant genetically modified (GM) maize 59122. The scope of the renewal application EFSA-GMO-RX-003 is for food and feed uses, import and processing, but excludes cultivation within the European Union (EU).

In delivering its scientific opinion, the GMO Panel took into account application EFSA-GMO-RX-003, additional information provided by the applicant, scientific comments submitted by the Member States and relevant scientific publications. The data received in the context of the renewal application EFSA-GMO-RX-003 contained: post-market environmental monitoring reports, an evaluation of the literature retrieved by a systematic search, updated bioinformatics analyses, and additional documents or studies performed by or on behalf of the applicant. The GMO Panel assessed these data for possible new hazards, modified exposure or new scientific uncertainties identified during the authorisation period and not previously assessed in the context of the original application.

In conclusion, under the assumption that the DNA sequence of the event in maize 59122 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that no new hazards or modified exposure and no new scientific uncertainties were identified that would change the conclusions of the original risk assessment on maize 59122 (EFSA, 2007).

[1] Regulation (EC) No 1829/2003 of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed. OJ L 268, 18.10.2003, p. 1–23.

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1. Introduction

1.1. Background

On 4 August 2016, the European Food Safety Authority (EFSA) received from the European Commission (DG SANTE) application EFSA-GMO-RX-003 for the renewal of authorisation of genetically modified (GM) maize 59122 (maize DAS-59122-7) for food and feed uses, import and processing submitted by Pioneer Overseas Corporation and Dow AgroSciences LLC within the framework of Regulation (EC) No 1829/2003. Before sending the application to EFSA, the European Commission (DG SANTE) checked whether the data submitted in the context of this renewal application were in line with the legal requirements laid down in Articles 11 and 23 of Regulation (EC) No 1829/2003.

After receiving the application EFSA-GMO-RX-003, and in accordance with Articles 5(2)(b) and 17(2)(b) of Regulation (EC) No 1829/2003, EFSA informed Member States and made the summary of the application available to the public on the EFSA website.[2]

On 16 September 2016, EFSA declared the application valid in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003. EFSA made the valid application available to Member States and the European Commission, and consulted nominated risk assessment bodies of Member States, including national Competent Authorities within the meaning of Directive 2001/18/EC following the requirements of Articles 6(4) and 18(4) of Regulation (EC) No 1829/2003, to request their scientific opinion. Member States had 3 months after the opening of the Member State commenting period (until 19 December 2016) to make their opinion known.

Following the submission of application EFSA-GMO-NL-2005-12 and the publication of the EFSA scientific opinion (EFSA, 2007), the placing on the market of maize 59122 for food/feed uses, except cultivation, was authorised by Commission Decision 2007/702/EC.[3] A copy of this authorisation was provided by the applicant.[4]

EFSA requested additional information on 24 October 2016 and 29 November 2016, and the applicant submitted it on 23 January 2017 and 26 January 2017, respectively.

In giving its scientific opinion to the European Commission, the Member States and the applicant, and in accordance with Articles 6(1) and 18(1) of Regulation (EC) No 1829/2003, EFSA has endeavoured to respect a time limit of 6 months from the acknowledgement of the valid application. As additional information was requested by the GMO Panel, the time limit of 6 months was extended accordingly, in line with Articles 6(1), 6(2), 18(1) and 18(2) of Regulation (EC) No 1829/2003.

According to Regulation (EC) No 1829/2003, this scientific opinion is to be seen as the report requested under Articles 6(6) and 18(6) of that Regulation and thus will be part of the EFSA overall opinion in accordance with Articles 6(5) and 18(5).

1.2. Terms of Reference as provided by the requestor

The GMO Panel was requested to carry out a scientific risk assessment on the data submitted in the context of a renewal of authorisation application for maize 59122 for food and feed uses, import and processing in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003.

Where applicable, any conditions or restrictions which should be imposed on the placing on the market and/or specific conditions or restrictions for use and handling, including post-market monitoring requirements based on the outcome of the risk assessment and, in the case of genetically modified organisms (GMOs) or food/feed containing or consisting of GMOs, conditions for the protection of particular ecosystems/environment and/or geographical areas should be indicated in accordance with Articles 6(5)(e) and 18(5)(e) of Regulation (EC) No 1829/2003.

The GMO Panel was not requested to give an opinion on information required under Annex II to the Cartagena Protocol. Furthermore, the GMO Panel did not consider proposals for labelling and methods of detection (including sampling and the identification of the specific transformation event in the food/feed and/or food/feed produced from it), which are matters related to risk management.

[2] Available online: http://registerofquestions.efsa.europa.eu/roqFrontend/questionDocumentsLoader?question=EFSA-Q-2016-00526

[3] Commission Decision of 24 October 2007 authorising the placing on the market of products containing, consisting of, or produced from genetically modified maize 59122 (DAS-59122-7) pursuant to Regulation (EC) No 1829/2003 of the European Parliament and of the Council. OJ L 285, 31.10.2007, p. 42-46.

[4] Dossier: Part II – Section 1.

2. Data and methodologies

2.1. Data

The data for application EFSA-GMO-RX-003 submitted by the applicant at the time of submission, or in reply to requests for additional information, are specified below.

The applicant clarified that the 59122 event sequence considered in the context of this renewal application was the sequence submitted in the original application EFSA-GMO-NL-2005-12 (EFSA, 2007), but corrected for sequencing errors affecting three single nucleotides[5] (EFSA GMO Panel, 2016).

According to the EFSA guidelines for renewal of applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015), the GMO Panel evaluated the data provided in the context of this maize 59122 renewal application under the assumption that the event sequence is identical to the corrected sequence that was newly determined and reported in this application.

2.1.1. Post-market monitoring reports[6]

Based on the outcome of the initial food and feed risk assessment, a post-market monitoring plan for monitoring of GM food/feed was not required by the authorising decisions. The implementation of a post-market environmental monitoring (PMEM) plan, consisting of a general surveillance plan to check for any adverse effects on the environment arising from maize 59122, was a condition for the authorisation. As no potential adverse environmental effects were identified in the environmental risk assessment (ERA) of maize 59122 (EFSA, 2007), case-specific monitoring was not considered necessary by the GMO Panel.

The applicant provided eight annual PMEM reports covering a reporting period from October 2007 to June 2015 and an update as of June 2016. The annual PMEM plans submitted by the applicant included (1) the description of a centralised system established by EuropaBio for the collection of information recorded by various operators (federations involved in maize (or bulk grain) import and processing) on any observed adverse effect(s) of the GMO on human health and the environment arising from handling of maize 59122; (2) the reports of the surveillance activities conducted by such operators; and (3) the review of relevant scientific peer-reviewed studies retrieved from literature searches.

The applicant provided an overall assessment of the general surveillance activities in the renewal dossier.

2.1.2. Systematic search and evaluation of literature[7]

In addition to the literature searches submitted within the annual PMEM reports, the applicant conducted an additional search, covering the complete duration of the event's authorisation (from 2007 to 2016), and following the principles outlined in the EFSA guidance on the application of systematic review methodology for food and feed safety assessment (EFSA, 2010).

The applicant performed a systematic search on 6 April 2016 of studies related to maize 59122 covering the authorisation period. The applicant used the databases Scopus and CAB Direct to identify relevant studies. Eligibility/inclusion criteria were defined *a priori* to categorise the relevance of retrieved studies. The search terms used included truncation symbols, synonyms, scientific and common names, brand and generic names and British and US variants (e.g. maize and corn) and were combined using the Boolean operators 'OR' and 'AND'. No restrictions (e.g. language, publication type) were applied with the exception of the time period. Altogether 458 unique studies were retrieved. After applying the eligibility/inclusion criteria, the applicant identified 11 relevant primary research studies published between 2007 and 2016.

2.1.3. Updated bioinformatics[8]

At the time of submission of the renewal dossier, the applicant provided a bioinformatics package for maize 59122 based on the corrected maize 59122 event sequence including the inserted sequences and sequences flanking the inserts. The data package included the analysis of (1) the potential disruption of any known maize genes by the 59122 insert; (2) the similarity of the newly

[5] Additional information: 23/1/2017.
[6] Dossier: Part II – Section 2.
[7] Dossier: Part II – Section 3.2.1.
[8] Dossier: Part II – Section 3.2.2 and Annex 11.

expressed proteins or any other open reading frame (ORF) defined from stop-to-stop codon, present within the insert or spanning the junction sites to known allergens or toxins; and (3) the insert containing any sequences of bacterial origin that would facilitate horizontal gene transfer (HGT) to microorganisms by homologous recombination.

2.1.4. Additional documents or studies provided by the applicant[9]

In line with the renewal guidance requirements (EFSA GMO Panel, 2015), the applicant provided an overview on the worldwide approvals of maize 59122, and a list and a summary of all unpublished studies produced, controlled or sponsored by the applicant, provided to the applicant by a third party, or performed over the course of the authorisation period and not previously submitted to the EU (Table 1). The relevance of the listed studies for molecular characterisation, human and animal safety and the environment was assessed. Based on the information provided, the GMO Panel requested from the applicant on 29 November 2016 the full study reports of three comparative analysis and five food and feed safety-related studies. The applicant submitted the requested information on 26 January 2017 and the study reports were assessed by the GMO Panel.

Table 1: List of all additional studies performed by Pioneer Overseas Corporation or Dow Agrosciences LLC over the course of the authorisation period (2007–2016) with regard to the evaluation of the safety of the food/feed and the risks of the food/feed to humans, animal or the environment from maize 59122

Study identification	Title
PHI-R035-Y15[(a)]	Segregation analysis of four maize generations containing event DAS-59122-7
PHI-2004-022/702[(a)]	Expressed trait protein concentration of a maize line containing event DAS-59122-7: U.S. and Canada test sites
PHI-2015-062[(a)]	Characterization of PAT protein derived from a microbial expression system
PHI-2004-022/701[(a),(c)]	Agronomic characteristics of a maize line containing event DAS-59122-7: U.S. and Canada test sites
PHI-2009-042/001[(a),(c)]	Agronomic characteristics of maize lines containing events DP-Ø9814Ø-6, DAS-Ø15Ø7-1, or DAS-59122-7: Europe test sites
PHI-2004-022/700[(a),(c)]	Nutrient composition of a maize line containing event DAS-59122-7: U.S. and Canada test sites
PHI-2015-055[(a),(c)]	Cry34Ab1 and Cry35Ab1 combination: acute oral toxicity study in mice
PHI-2015-059[(a),(c)]	Cry34Ab1: Acute oral toxicity study in mice
PHI-2015-060[(a),(c)]	Cry35Ab1: Acute oral toxicity study in mice
PHI-2015-074[(a),(c)]	PAT: Acute oral toxicity study in mice
PHI-2005-118[(a)]	Evaluation of nutritional equivalency of Herculex* RW corn grain in the diets of beef steers
PHI-2003-016[(a)]	Chile field production of grain from maize lines containing event: DAS-59122-7
PHI-2003-066[(a)]	Plant growth and tissue sample collection for developing seed and leaf tissue from event DAS-59122-7 and control plants
PHI-2004-029[(a)]	U.S. field production of grain from maize line containing event: DAS-59122-7
PHI-2004-093[(a)]	Field production of grain from hybrid maize line DAS-59122-7: Chile
PHI-2005-028[(a)]	Field production of grain and silage from maize line 59122
PHI-2005-064[(a)]	Field production of grain from hybrid maize line 59122
120936[(b),(c)]	*In vitro* simulated intestinal fluid digestibility study of phosphinothricin acetyltransferase (PAT) protein
050072[(b)]	Quantification of Cry34Ab1 and Cry35Ab1 Proteins in Wet-Milling and Dry-Milling Corn Processed Products by Enzyme-Linked Immunosorbent Assay (ELISA)

(a): Performed by Pioneer Hi-Bred International, Inc.
(b): Performed by Dow Agrosciences.
(c): Studies for which the full report was requested by the GMO Panel.

[9] Dossier: Part II – Sections 2.3.1.1, 3.1 and additional information: 26/1/2017.

2.1.5. Overall assessment as provided by the applicant[10]

In line with the requirements listed in the renewal guidance (EFSA GMO Panel, 2015), the applicant provided an overall assessment on whether the collected information leads to the identification of new hazards or modified exposure, or adds new scientific uncertainties.

2.1.6. Monitoring plan and proposal for improving the conditions of the original authorisation[11]

The applicant indicated in the dossier that the environmental monitoring plan is appropriate and does not need any changes.

2.2. Methodologies

The GMO Panel assessed the data submitted in the context of the renewal of the authorisation application of maize 59122 for food and feed uses, import and processing in accordance with Articles 11 and 23 of Regulation (EC) No 1829/2003. The GMO Panel took into account the requirements described in its guideline for the risk assessment of renewal applications of GM food and feed authorised under Regulation (EC) No 1829/2003 (EFSA GMO Panel, 2015).

The comments raised by Member States are addressed in Annex G of EFSA's overall opinion[12] and were taken into consideration during the scientific risk assessment.

3. Assessment

3.1. Evaluation of the post-market environmental monitoring reports

During the general surveillance activities covering the authorisation period of maize 59122, no adverse effects were reported by the applicant.

3.2. Evaluation of the systematic search and evaluation of literature

Ten of the 11 relevant primary research studies identified by the applicant have already been assessed by the GMO Panel (EFSA GMO Panel, 2013) and it was concluded that none of them raised any safety concerns. The GMO Panel assessed the remaining publication, Ferreira et al. (2015), in which it was reported that the agronomic and phenotypic characteristics and nutritional composition of grains and forage of maize 59122 did not differ from its non-GM comparator. The GMO Panel considered that the study did not give rise to any safety concern for human and animal health and the environment which would change the original risk assessment conclusions on maize 59122.

3.3. Evaluation of the updated bioinformatics

The results of the bioinformatics analyses on the corrected 59122 event sequence confirmed that no known endogenous genes were disrupted by the insert. Analyses of the amino acid sequence of the newly expressed Cry34Ab1, Cry35Ab1 and phosphinothricin acetyltransferase (PAT) proteins revealed no significant similarities to toxins and allergens. In addition, bioinformatics analyses of the newly created ORFs within the insert or spanning the junctions with genomic DNA revealed no significant similarities to toxins and allergens.

The sequence identity analysis of the regions of bacterial origin in maize 59122 did not identify elements with sufficient length and identity to support homologous recombination (EFSA, 2015). There is no information that would change the previous conclusion of the GMO Panel that the unlikely, but theoretically possible, horizontal transfer of recombinant genes from maize 59122 to bacteria does not raise any environmental safety concern.

[10] Dossier: Part II – Sections 2.3.1.
[11] Dossier: Part II – Section 2.5.
[12] Available online: http://registerofquestions.efsa.europa.eu/roqFrontend/questionLoader?question=EFSA-Q-2017-00433

3.4. Evaluation of the additional documents or studies provided by the applicant

The GMO Panel evaluated the summary and/or the full study reports of the relevant studies provided (Table 1). This new information did not raise any concern for human and animal health, and the environment which would change the original risk assessment conclusions on maize 59122.

3.5. Evaluation of the overall assessment as provided by the applicant

The GMO Panel evaluated the overall assessment provided by the applicant and did not identify new hazards, relevant changes in the exposure to products containing maize 59122 or new scientific uncertainties which would change the original risk assessment conclusions of maize 59122.

3.6. Evaluation of the monitoring plan and proposal for improving the conditions of the original authorisation

The PMEM plan followed by the applicant consists mainly of general surveillance of imported GM maize plant material, including maize 59122. This general surveillance is coordinated by EuropaBio and implemented by selected operators (federations involved in maize import and processing). In addition, the applicant reviews relevant scientific publications retrieved from literature searches on an annual basis. As mentioned in Section 2.1.6, the applicant considers that this plan does not need any changes. The GMO Panel is of the opinion that the scope of the plan provided by the applicant is consistent with the scope of maize 59122 but notes that monitoring is related to risk management, and thus the final adoption of the PMEM plan falls outside the mandate of EFSA.

4. Conclusions

Under the assumption that the DNA sequence of the event in maize 59122 considered for renewal is identical to the corrected sequence of the originally assessed event, the GMO Panel concludes that no new hazards or modified exposure and no new scientific uncertainties were identified for the application for renewal that would change the conclusions of the original risk assessment on maize 59122 (EFSA, 2007).

Documentation provided to EFSA

1) Letter from the European Commission to EFSA received on 4 August 2016 for the continued marketing of genetically modified maize 59122 in accordance with articles 11 and 23 of Regulation (EC) No 1829/2003 by Pioneer Overseas Corporation and Dow AgroSciences Ltd. (EFSA-GMO-RX-003).
2) Acknowledgement letter dated 30 August 2016 from EFSA to European Commission.
3) Letter from EFSA to applicant dated 16 September 2016 delivering the 'Statement of Validity' for application EFSA-GMO-RX-003.
4) Letter from EFSA to applicant dated 24 October 2016 requesting additional information and stopping the clock.
5) Letter from EFSA to applicant dated 29 November 2016 requesting additional information and maintaining the clock stopped.
6) Letter from applicant to EFSA received on 2 December 2016 asking for an extension of deadline to submit information requested on 24 October 2016.
7) Letter from applicant to EFSA received on 5 January 2017 accepting the request for additional information and deadline of EFSA letter dated 29 November 2016.
8) Email from EFSA to applicant accepting the extension of deadline requested on 2 December 2016.
9) Letter from applicant to EFSA received on 23 January 2017 providing additional information following EFSA request of 24 October 2016.
10) Email from EFSA to applicant of 24 January 2017 acknowledging receipt of additional information and informing that clock remains stopped.
11) Letter from applicant to EFSA received on 26 January 2017 providing additional information following EFSA request of 29 November 2016.

Email from EFSA to applicant of 26 January 2017 acknowledging receipt of additional information and restarting the clock.

References

EFSA (European Food Safety Authority), 2007. Opinion of the Scientific Panel on Genetically Modified Organisms on an application (reference EFSA-GMO-NL-2005-12) for the placing on the market of insect-resistant genetically modified maize 59122, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International, Inc. and Mycogen Seeds, c/o Dow Agrosciences LLC. EFSA Journal 2007;5(4):470, 25 pp. https://doi.org/10.2903/j.efsa.2007.470

EFSA (European Food Safety Authority), 2010. Application of systematic review methodology to food and feed safety assessments to support decision making. EFSA Journal 2010;8(6):1637, 90 pp. https://doi.org/10.2903/j.efsa.2010.1637

EFSA (European Food Safety Authority), 2015. Explanatory note on DNA sequence similarity searches in the context of the assessment of horizontal gene transfer from plants to microorganisms. EFSA Supporting Publication 2015;12(12):EN–916, 10 pp. https://doi.org/10.2903/sp.efsa.2015.en-916

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2013. Scientific Opinion on an application from Pioneer Hi-Bred International and Dow AgroSciences LLC (EFSA-GMO-NL-2005-23) for placing on the market of genetically modified maize 59122 for food and feed uses, import, processing and cultivation under Regulation (EC) No 1829/2003. EFSA Journal 2013;11(3):3135, 104 pp. https://doi.org/10.2903/j.efsa.2013.3135

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), 2015. Guidance for renewal applications of genetically modified food and feed authorised under Regulation (EC) No 1829/2003. EFSA Journal 2015;13(6):4129, 8 pp. https://doi.org/10.2903/j.efsa.2015.4129

EFSA GMO Panel (EFSA Panel on Genetically Modified Organisms), Naegeli H, Birch AN, Casacuberta J, De Schrijver A, Gralak MA, Guerche P, Jones H, Manachini B, Messéan A, Nielsen EE, Nogué F, Robaglia C, Rostoks N, Sweet J, Tebbe C, Visioli F, Wal J-M and Paraskevopoulos K, 2016. Statement on the risk assessment of new sequencing information on GM maize event DAS-59122-7. EFSA Journal 2016;14(12):4639, 7 pp. https://doi.org/10.2903/j.efsa.2016.4639

Ferreira FS, Nozawa SR and de Souza JC, 2015. Consequences of gene stacking by hybridization in transgenic plants. Euphytica, 206, 319–329.

Abbreviations

ERA	environmental risk assessment
GM	genetically modified
GMO	genetically modified organisms
HGT	horizontal gene transfer
ORFs	open reading frames
PAT	phosphinothricin acetyltransferase
PMEM	post-market environmental monitoring report